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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,679	04/16/2004	Ganesaratnam K. Balendiran	54435.8003.US01	9599

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,679	BALENDIRAN, GANESARATNAM K.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5, drawn to a method of treating a subject in need of modulating the activity of aldose reductase comprising administering to the subject a fibrate, classified in class 514, subclass 571. Please note the additional Species Election Requirement outlined below if Group I is elected.

II. Claims 6-10, drawn to a method of treating a neoplasm comprising contacting the neoplasm with a fibrate, classified in class 514, subclass 571. Please note the additional Species Election Requirement outlined below if Group II is elected.

III. Claims 11-13, drawn to a method of modulating the activity of aldose reductase in a cell comprising contacting the cell with a fibrate, classified in class 514, subclass 571. Please note the additional Species Election Requirement outlined below if Group III is elected.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different modes of operation and effects. For example, the method claims of group I require modulation of aldose reductase whereas the method claims of group II do not. In addition, the patient

populations of groups I and II do not overlap. The patient population (or treatment group) of group II requires the presence of a neoplasm with no requirement that that aldose reductase activity be modulated. However, the patient population of group I requires administration to a subject in need of modulating the activity of aldose reductase. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions II and III are directed to related methods of using fibrates. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different modes of operation and effects. For example, the method claims of group II do not require modulation of aldose reductase whereas the method claims of group III do. In addition, the treatment groups of groups II and III do not overlap. The patient population (or treatment group) of group II requires the presence of a neoplasm with no requirement that that aldose reductase activity be modulated. However, the claims of group III require administration of a fibrate to a cell and further require that aldose reductase activity be modulated. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and III are directed to related methods of modulating aldose reductase activity. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or

effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design. For example, the claims of group I require administration to a subject whereas the claims of group III only require contacting "a cell" with a fibrate. Although both groups require modulation of aldose reductase, the treatment groups are distinct. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

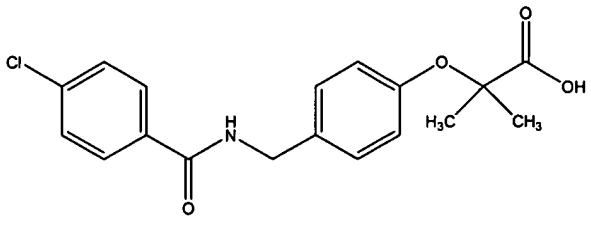
The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

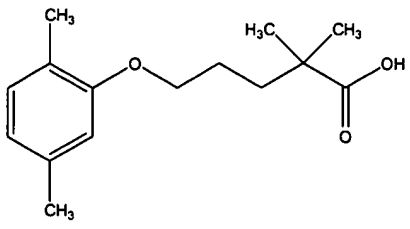
either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Election of Species Requirement upon Election of Group I

The claims of group I are directed to the following patentably distinct species: A) the various conditions wherein modulation of aldose reductase is needed; B) the multitude of species encompassed by the genus "fibrate"; and C) the multitude of chemotherapeutics encompassed by claim 5. The species are independent or distinct because the patient populations encompassed by the claims of group I do not overlap in scope and agents encompassed by the genus "fibrates" and "chemotherapeutics" have different structures that would require a different search. Dependent claim 4 lists a number of conditions (species) encompassed by the genus wherein a subject is in need of modulating aldose reductase. However, these conditions have divergent patient populations that do not overlap. For example, a patient with cardiovascular disease does not, *a priori*, overlap with a patient having a cataract and *vice versa*. Further, because the genus of fibrates and chemotherapeutics encompass compounds with distinct structures, to search the entire genus would present an undue search burden. For example, fibrates include the following structures:



Bezafibrate



Gemfibrozil

Clearly, a search for bezafibrate would not result in the identification of gemfibrozil and *vice versa* because these two fibrates have limited structural similarity. Further, the genus of fibrates is defined as a class of amphipathic carboxylic acids. Similarly, the genus "chemotherapeutics" recited in claim 5 encompasses thousands of agents with diverse structures and modes of action. As such, to search such a broad class would be an undue search burden.

Therefore, upon election of the claims of group I, applicant is further required to elect one specie from the each of the following genus:

A) a single condition whereby there is a need of modulating the activity of aldose reductase (*e.g.* diabetes, neoplasm, thrombosis, etc.)

B) a single fibrate (*e.g.* bezafibrate, gemfirizil, etc.)

C) a single chemotherapeutic agent (*e.g.* 5-FU, taxol, etc.)

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 3-5 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Election of Species Requirement upon Election of Group II

The claims of group II are directed to the following patentably distinct species: A) the various species of "neoplasms" recited in claim 6; B) the multitude of species encompassed by the genus "fibrate"; and C) the multitude of chemotherapeutics encompassed by claim 10. The species are independent or distinct because the treatment of different neoplasms requires administration to divergent patient populations. Further, agents encompassed by the genus "fibrates" and "chemotherapeutics" have different structures that would require a different search. Dependent claim 9 lists a number of distinct neoplasms (species) encompassed by the genus neoplasm recited in claim 6. However, treatment of each neoplasm requires administration of a fibrate to a different patient population and requires a different treatment modality. For example, the treatment of leukemia (a blood borne neoplasm) and solid tumors requires different administration doses, schedules and modes of administration. Further, because the genus of fibrates and chemotherapeutics encompass compounds with distinct structures, to search the entire genus would present an undue search burden (see above).

Therefore, upon election of the claims of group II, applicant is further required to elect one specie from the each of the following genus:

A) a single specie of neoplasm (*e.g.* AML, colon cancer, prostate cancer, etc.)

B) a single fibrate (*e.g.* bezafibrate, gemfirizil, etc.)

C) a single chemotherapeutic agent (*e.g.* 5-FU, taxol, etc.)

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6 and 8-10 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Election of Species Requirement upon Election of Group III

The claims of group III are directed to the following patentably distinct species: the multitude of species encompassed by the genus "fibrate." The species are independent or distinct because agents encompassed by the genus "fibrates" have different structures that would require a different search. As such, to search the entire genus would present an undue search burden (see above).

Therefore, upon election of the claims of group III, applicant is further required to elect a single fibrate for prosecution on the merits.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 11 and 13 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

September 14, 2006

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER